PCT/IE 04 / 00106

Patents Office
Government Buildings
Hebron Road
Kilkenny

I HEREBY CERTIFY that annexed hereto is a true copy of documents filed in connection with the following patent application:

Application No.	S2003/0579
Date of Filing	6 August 2003
Applicant	BRIVANT RESEARCH & DEVELOPMENT LIMITED, an Irish company of Unit 6, Campus Innovation Center, Newcastle Road, Galway, Ireland.

Dated this 12 day of August 2004.

An officer authorised by the
Controller of Patents, Designs and Trademarks.

S030579

Application No. _____

FORM NO. 1

REQUEST FOR THE GRANT OF A PATENT

PATENTS ACT, 1992

The Applicant(s) named herein hereby request(s)

☐ the grant of a patent under Part II of the Act

☒ the grant of a short-term patent under Part III of the Act

on the basis of the information furnished hereunder.

1. Applicant(s)

Name

BRIVANT RESEARCH & DEVELOPMENT LIMITED

Address

Unit 6, Campus Innovation Center, Newcastle Road, Galway, Ireland.

Description/Nationality

An Irish company.

2. Title of Invention

"A guide wire for use with a catheter"

3. Declaration of Priority on basis of previously filed application(s) for same invention (Sections 25 & 26)

Previous filing date	Country in or for which filed	Filing No.

4. Identification of Inventor(s)

Name(s) of person(s) believed by Applicant(s) to be the inventor(s)

HENRY WILLIAM LUPTON

Address

Minehill House, Renville West, Oranmore, County Galway, Ireland; an Irish citizen.

5. **Statement of right to be granted a patent (Section 17 (2) (b))**
The applicant has derived the right to be granted a Patent from the inventor by virtue of a Deed of Assignment dated July 22, 2003.

6. **Items accompanying this request – tick as appropriate**

(i) [X] Prescribed filing fee (€ 60.00)

(ii) [ ] Specification containing a description and claims

[X] Specification containing a description only

[X] Drawings referred to in description or claims

(iii) [ ] An abstract

(iv) [ ] Copy of previous application(s) whose priority is claimed

(v) [ ] Translation of previous application whose priority is claimed

(vi) [X] Authorisation of Agent (this may be given at 8 below if this Request is signed by the Applicant(s))

7. **Divisional Application(s)**
The following information is applicable to the present application which is made under Section 24 –

Earlier Application No: .....
Filing Date: .....

8. **Agent**
The following is authorised to act as agent in all proceedings connected with the obtaining of a patent to which this request relates and in relation to any patent granted –

Name	Address
F.F. GORMAN & CO.	15 Clanwilliam Square, Dublin 2, Ireland.

9. **Address for Service (if different from that at 8)**
F.F. GORMAN & CO., at its address as recorded for the time being in the Register of Patent Agents.

Signed

BRIVANT RESEARCH & DEVELOPMENT LIMITED

BY: _____

CAPACITY: Managing Director

Date July 22, 2003.

"A guide wire for use with a catheter"

The present invention relates to a guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject, and in particular though not limited to a guide wire for use with a catheter.

Guide wires for locating a distal end of a catheter in a remote site in the body of a human or animal subject are known. Such guide wires are commonly used for guiding a catheter along narrow blood vessels to a site in the cardiovascular system of the subject for enabling cardiovascular procedures to be carried out. Typically, the guide wire is introduced through a cannula into a suitable blood vessel in the thigh or arm of the subject and is passed through the blood vessels to the desired site in the cardiovascular system. Once the guide wire has reached the desired site, the catheter is then advanced over the guide wire to the site. Guide wires are also extensively used to guide a catheter to other sites through the venal system, and also to sites in the renal system, as well as to other sites in human and animal subjects through other accessing systems.

Due to the relatively narrow diameter of the blood vessels through which the guide wire has to pass, and in particular, due to the tortuous nature of the blood vessels of the cardiovascular and other venal systems, and the number of branching blood vessels, it is essential that the guide wire be of a construction which facilitates bending of the guide wire so that the guide wire can be bent around corners, and can be directed into a desired one of branching blood vessels. Various attempts

have been made to provide such guide wires, for example, such a guide wire is described in U.S. Patent Specification No. 4,545,390 of Leary and U.S. Patent Specification No. 4,080,706 of Heilman, et al. While the guide wires described in these two prior art specifications are flexible and suitable for bending around corners of the blood vessels of the venal system, they suffer from a disadvantage in that it is difficult to initially direct the guide wire around the corner, and in particular, it is difficult to direct the guide wire from one blood vessel into a branching blood vessel. In order to overcome this problem, the distal portion of known guide wires are shaped for facilitating bending of the distal portion to form a curved distal portion, which can then be directed towards a branching blood vessel into which the guide wire is to be directed, and also for facilitating aligning the guide wire with a corner or bend in the venal system. However, in general, shaping the distal portion of such guide wires in order to facilitate bending the guide wire into a curved portion leads to a reduction in the torsional rigidity of the distal portion. This is undesirable, since drag exerted on the distal portion by the venal system can lead to twisting of the distal portion when the proximal portion of the guide wire is being rotated about a central axis of the guide wire for aligning the curved distal portion with a bend or corner in the venal system or with a branching blood vessel into which the guide wire is to be directed.

A further, and indeed, a more serious problem associated with such guide wires is that once the distal portion of the guide wire has been bent to form a desired curvature, prior to being inserted into the venal or renal system of a subject, once the guide wire is inserted into the venal or renal system, it is not possible to alter the

curvature of the bent distal portion. This is particularly undesirable where the guide wire is to be used in a venal system of blood vessels of varying cross-section, and in particular, where branches of the venal system branch off at different angles. Accordingly, there is a need for a guide wire which overcomes this problem.

The present invention is directed towards providing such a guide wire.

According to the invention there is provided an elongated guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or an animal subject, the guide wire defining a longitudinally extending axis, and extending axially between a distal end for accessing the remote site, and a spaced apart proximal end, the distal end terminating in a pair of curvature inducing members constrained to move parallel to each other, and being secured together at the distal end so that when one of the curvature inducing members is moved relative to the other a curvature configuration is imposed in a distal portion of the guide wire adjacent the distal end thereof.

Preferably, the radius of the curvature imposed in the distal portion of the guide wire is selectable.

In one embodiment of the invention a means for moving the curvature inducing members relative to each other is provided, and preferably, the means for moving the curvature inducing members relative to each other is located adjacent the proximal end of the guide wire.

In one embodiment of the invention the curvature inducing members are longitudinal members extending in a generally axial direction relative to the guide wire, and preferably, terminate in a tip portion which forms the tip of the guide wire. Advantageously, the curvature inducing members are secured together at the tip portion.

In another embodiment of the invention one of the curvature inducing members is provided with a groove defining a longitudinally extending axis which preferably extends parallel to the axis of the guide wire, and the other curvature inducing member is provided with a tongue slideably engageable in the groove, the tongue and groove being arranged for constraining the curvature inducing members to move parallel to each other.

In a further embodiment of the invention one of the curvature inducing members forms the guide wire, and preferably, the curvature inducing member having the groove provided therein forms the guide wire. Advantageously, the groove extends the length of the guide wire, and preferably, a connecting means extends from the other of the curvature inducing members to the means for moving one of the curvature inducing members relative to the other. Advantageously, the connecting means extends through the groove, and preferably, the connecting means comprises a connecting wire, and ideally, the proximal end of the connecting means forms the means for moving one of the curvature inducing members relative to the other.

Alternatively, a longitudinally extending bore extends through the one of the curvature inducing means which is provided with the groove, and the connecting means extends through the longitudinally extending bore.

Preferably, the curvature inducing members are of a flexible material, and advantageously, are of a flexible resilient material.

In another embodiment of the invention the curvature inducing members are of a metallic material.

In another embodiment of the invention the curvature inducing members are of a polymer material. In a still further embodiment of the invention the curvature inducing members are manufactured from a combination of a metallic material and a polymer material.

In a further embodiment of the invention the curvature inducing members are formed of a suitable material which may be a polymeric material or other plastics material, or a metal material, for example, stainless steel, platinum alloy, or other suitable metal material.

In one embodiment of the invention the tip portion formed by the curvature inducing members is a bulbous tip.

In another embodiment of the invention a sleeve is provided around the distal end of the guide wire, and preferably, the sleeve extends from the bulbous tip.

In one embodiment of the invention the sleeve is of flexible material.

In another embodiment of the invention the sleeve is of a radiopaque material, or terminates in its distal end in a radiopaque material.

In another embodiment of the invention the sleeve is of stainless steel and terminates in the radiopaque material.

In one embodiment of the invention the radiopaque material of the sleeve is selected from one or more of the following materials:

platinum,

platinum alloy,

gold,

tantalum.

In a further embodiment of the invention the sleeve is formed by a tightly coiled spring wound around the guide wire adjacent the distal end.

In an alternative embodiment of the invention the sleeve is of plastics material and terminates in the radiopaque material.

In a still further embodiment of the invention the sleeve comprises a combination of a tightly coiled spring and the sleeve of plastics material.

The invention also provides in combination the guide wire according to the invention and a catheter.

The invention will be more clearly understood from the following descriptions of an embodiment thereof which is given by way of example only with reference to the accompanying drawings in which:

Fig. 1 is a cutaway side elevational view of a guide wire according to the invention,

Fig. 2 is a perspective view of a portion of the guide wire of Fig. 1,

Fig. 3 is another perspective view of the portion of the guide wire of Fig. 2,

Fig. 4 is a transverse cross-sectional end elevational view of the portion of the guide wire of Fig. 2, on the line IV-IV of Fig. 1, and

Fig. 5 is a perspective view of the portion of the guide wire of Fig. 2 with part of the guide wire in use in a different position.

Referring to the drawings, there is illustrated a guide wire according to the invention

indicated generally by the reference numeral 1 for use with a catheter (not shown) for guiding the catheter to a remote site in the body of a human subject. The guide wire 1 is particularly suitable for accessing a remote site in the cardiovascular system of the subject for, in turn, guiding a catheter to a remote site in the cardiovascular system, for example, for guiding a catheter to a remote site in the heart of a subject. However, it will be readily apparent to those skilled in the art that the guide wire 1 is suitable also for accessing any remote site in a human or animal subject, be it in a vasculature system, the venal system, a renal system, or other system. For example, the guide wire 1 is suitable for accessing renal vessels, neuro-vasculature systems, the fallopian tubes, and other such vessels and sites.

The guide wire 1 extends between a distal end 3 and a proximal end 4 and defines a central longitudinally extending axis 5. The guide wire 1 comprises an elongated main member 7 of flexible resilient material, in this embodiment of the invention a polymeric material extending from the proximal end 4 to the distal end 3. The main member 7 terminates in a tip portion 9 at the distal end 3 which is also of polymeric material, and typically is formed internally with the main member 7. A flexible sleeve 10 extends around the main member 7 and is engaged on the tip portion 9 and extends along the main member 7 from the tip portion 9 and engages the main member 7 at 14. In this embodiment of the invention, the sleeve is formed by a tightly wound spring of radiopaque material, namely, a platinum alloy material.

The main member 7 terminates in a curvature inducing distal portion 15 which forms one of a pair of curvature inducing members for facilitating the imposition of a

curvature configuration on the distal portion 15 of the guide wire 1. The other of the pair of curvature inducing members is an elongated member 16 of flexible resilient material, in this case also a polymeric material which is also secured to the tip portion 9 by any suitable means, for example, heat welding, adhesive bonding or the like. The curvature inducing member 16 extends longitudinally and axially from the tip portion 9. A tongue 17 extending axially along the curvature inducing member 16 slideably engages a groove 18 extending axially along the distal portion 15 of the main member 7. The slideable co-operating action of the tongue 17 in the groove 18 constrains the curvature inducing member 16 to move parallel relative to the distal portion 15 of the main member 7, and since the distal portion 15 and the curvature inducing member 16 are secured together to the tip portion 9, axial movement of the curvature inducing member 16 relative to the distal portion 15 causes the distal portion 15 and the curvature inducting member 16 to curve relative to each other, see Fig. 5, thereby inducing curvature in the guide wire 1 at the distal portion 15 for facilitating directing the guide wire through the venal, renal or other system of a subject and for facilitating branching off from one vessel to another of the venal, renal or other system. The curvature inducing member 16 extends from the tip portion 9 along the curvature inducing distal portion 15 of the main member 7 a distance corresponding to the length of the curvature inducing distal portion 15 along which it is desired to impose curvature, and terminates at a position 19. However, if desired, the curvature inducing member 16 could extend a greater or shorter distance along the distal portion 15 of the main member 7.

In this embodiment of the invention, the groove 18 extends the length of the main

member 7. A connecting means provided by a connecting wire 20 coupled to the curvature inducing member 16 extends through the groove 18 to the proximal end 4 of the guide wire 1 for facilitating moving the curvature inducing member 16 relative to the curvature inducing distal portion 15 of the main member 7.

The tip portion 9 is hemispherical to form a leading portion of the guide wire 1 for facilitating guiding of the guide wire 1 through the venal, renal or other system of the subject without causing damage to the vessels of the system, and the sleeve 10 extends to engage the main member 7 at 14 for protecting the curvature inducing portion 15 of the main member 7 and the curvature inducing member 16, and also for providing a smooth outer surface of the guide wire 1.

In use, the guide wire 1 is inserted into the venal, renal or other system of the subject at an appropriate location. Where it is desired to branch from one vessel to another, the connecting wire 20 is urged axially inwardly or outwardly of the groove 18 of the main member 7 for urging the curvature inducing member 16 relative to the curvature inducing distal portion 15 for inducing curvature in the curvature inducing distal portion 15 and the curvature inducing member 16. The degree of curvature is selectable by varying the amount of relative axial movement of the connecting wire 20 relative to the main member 7. After the guide wire has been branched from one vessel to the next, the distal portion 15 of the guide wire 1 is straightened by axially urging the connecting wire 20 into or out of the groove 18 of the main member 7 in the reverse direction to that for which it was moved for inducing the curvature.

The guide wire according to the invention has many advantages. Firstly, curvature can be selectively imposed on the distal portion of the guide wire when the guide wire is in the venal, renal or other system of the subject. Thus, the curvature can be selectively imposed on the distal portion of the guide wire when the guide wire is at or about to approach a branching vessel for urging the connecting wire into the branching vessel. Additionally, a further and particularly important advantage of the invention is that the imposed curvature on the distal portion of the guide wire can be removed once the guide wire has been urged into the branching vessel. A further and particularly important advantage of the invention is that the degree of curvature to be imposed on the distal portion of the guide wire can be varied to take account of branching vessels which branch at different angles from a main vessel.

While the guide wire has been described as being of specific materials, any other suitable materials may be used without department from the scope of the invention. Additionally, while the curvature inducing members have been described as being constrained to move parallel to each other by virtue of one of the curvature inducing members engaging the other by means of a tongue and groove arrangement, any other suitable means for constraining the two members to move parallel to each other may be provided.

It is also envisaged that while one of the curvature inducing members has been described as being formed by the distal portion of the main wire of the guide wire, the two curvature inducing members could be provided separately from the main member forming the guide wire. Indeed, it is envisaged that in certain cases, the

main member may be an elongated tubular member having a longitudinally extending central bore and one of the curvature inducing members would be secured to the main member at its distal end, and the connecting wire connecting the other curvature inducing member to the proximal end of the guide wire may extend through a central bore in the tubular member.

The invention is not limited to the embodiments hereinbefore described, which may be varied in construction and detail.

F.F. GORMAN & CO.

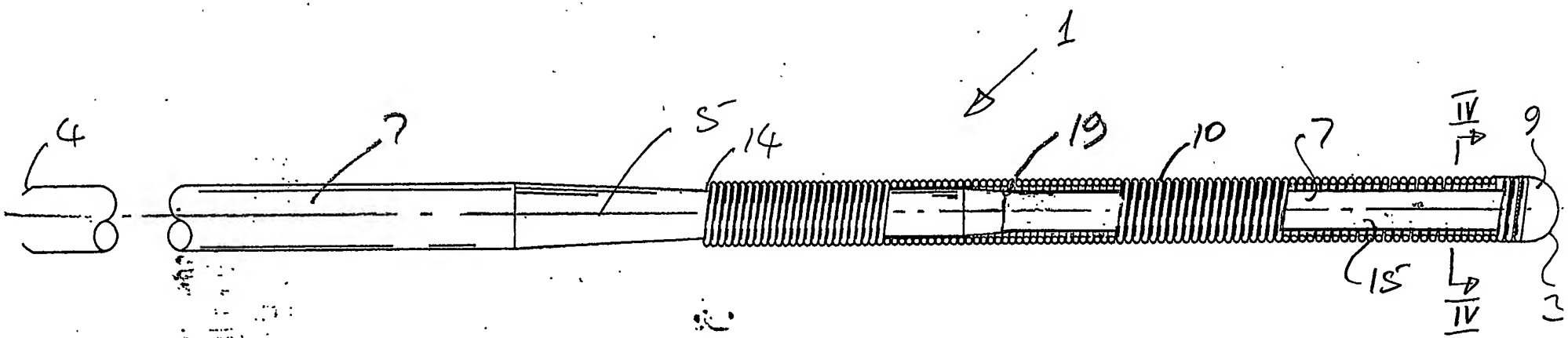

FIG 1

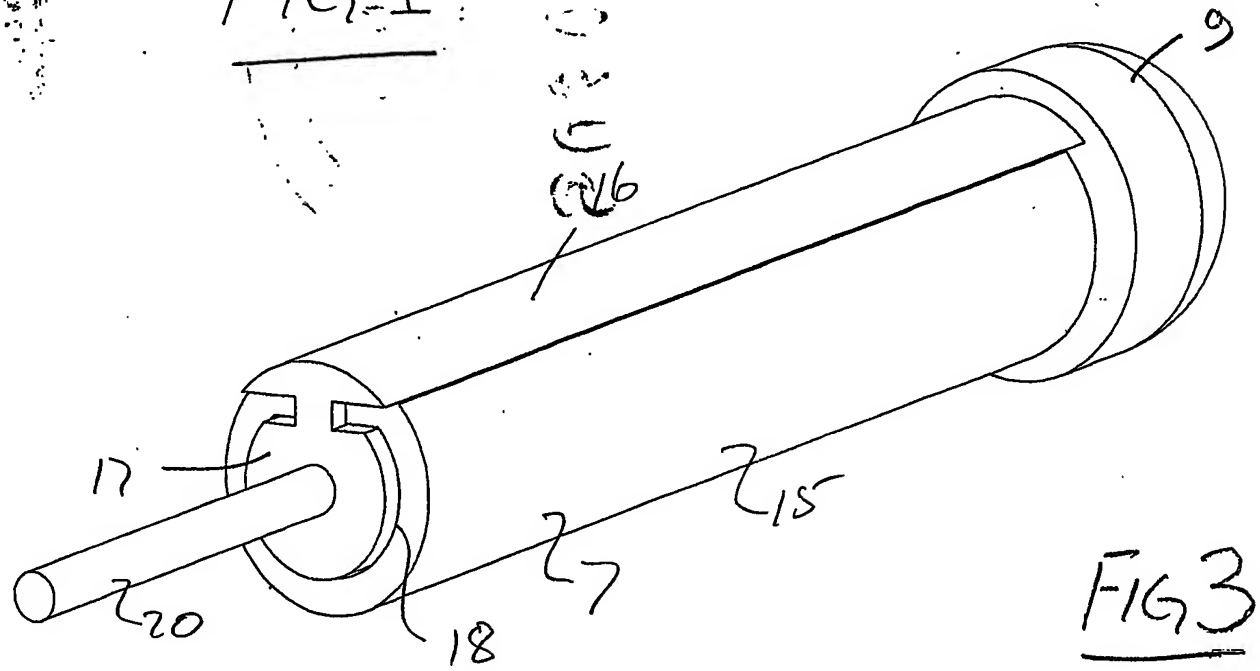

FIG 3

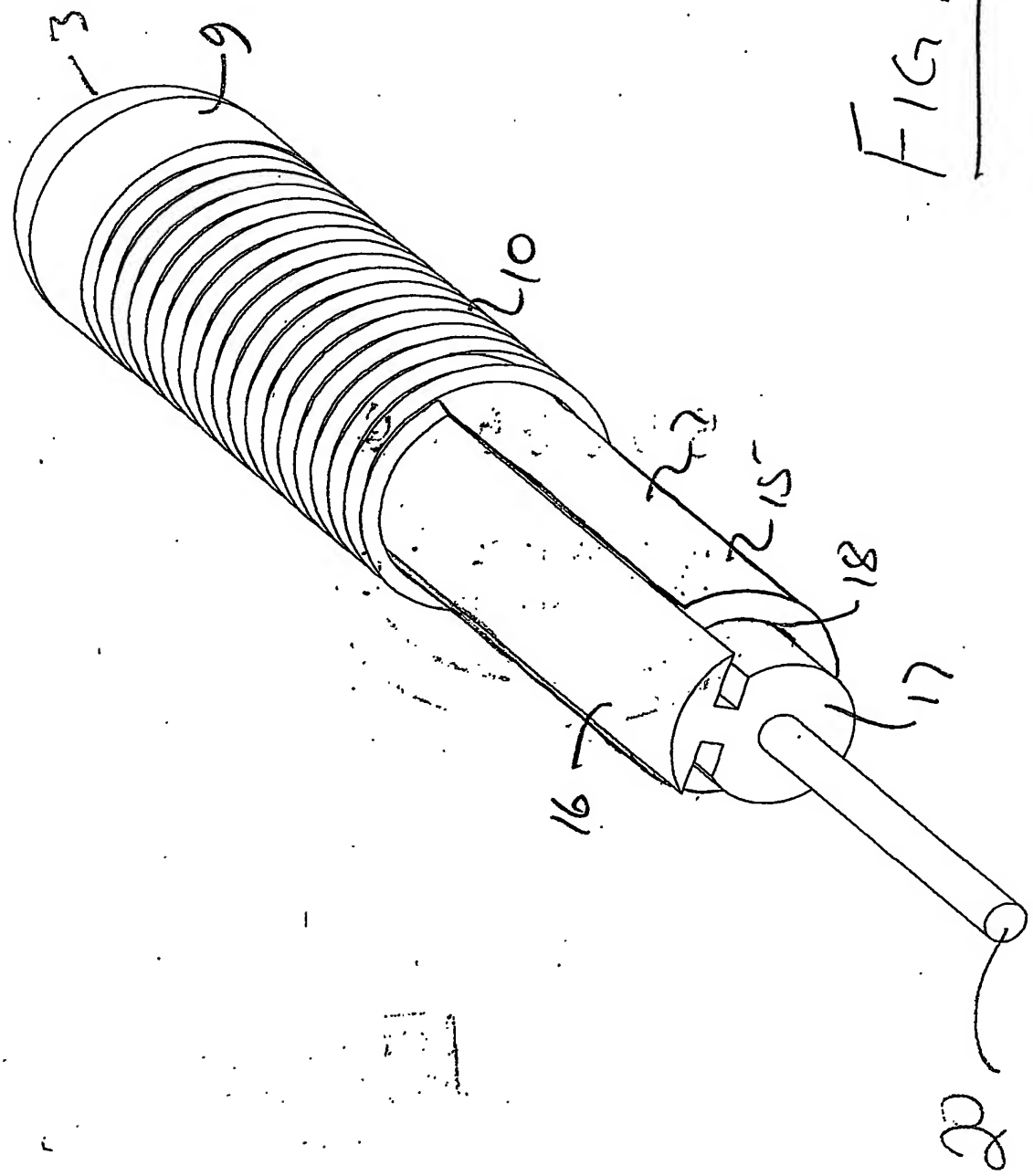

FIG 2

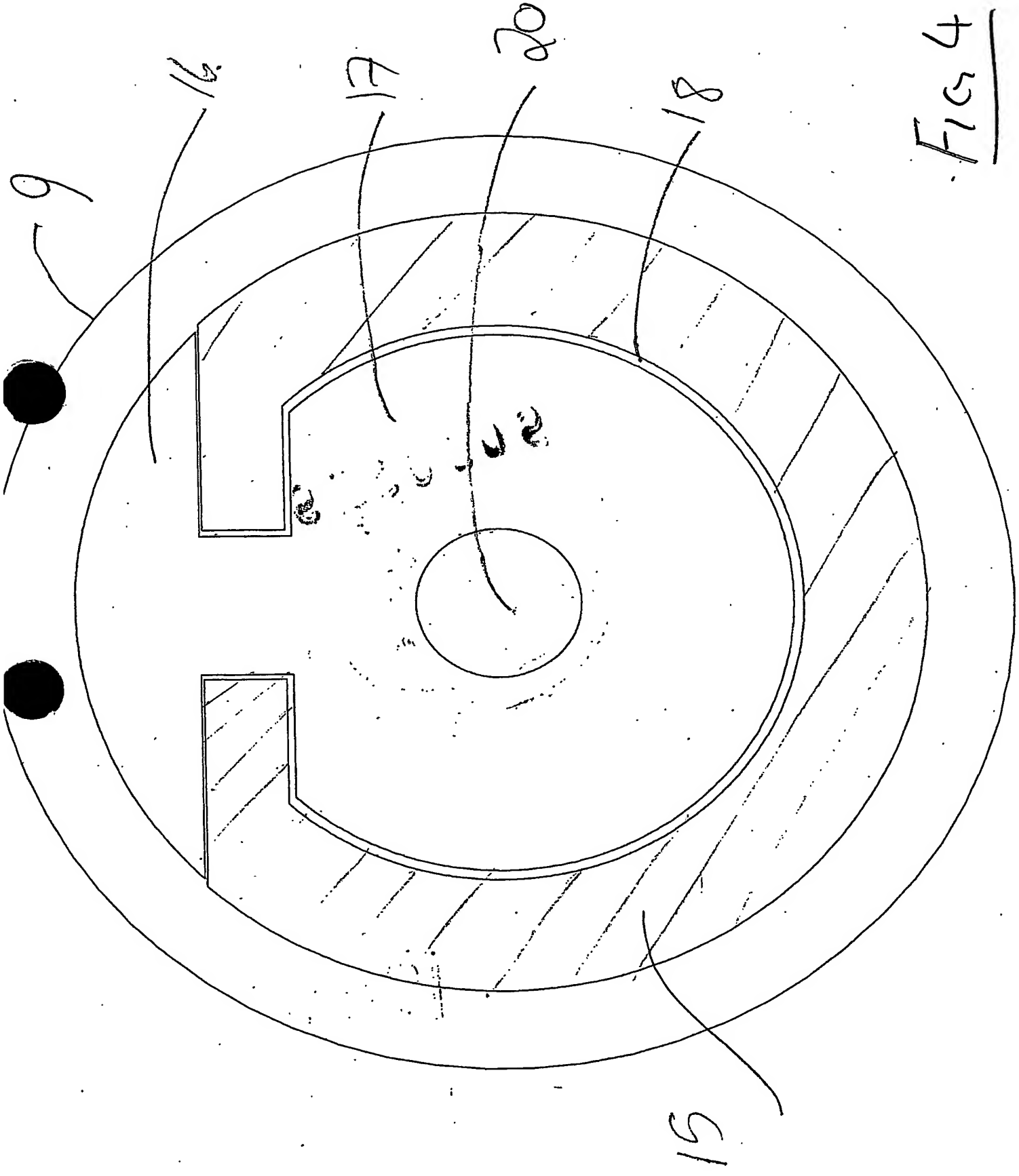

Fig 4

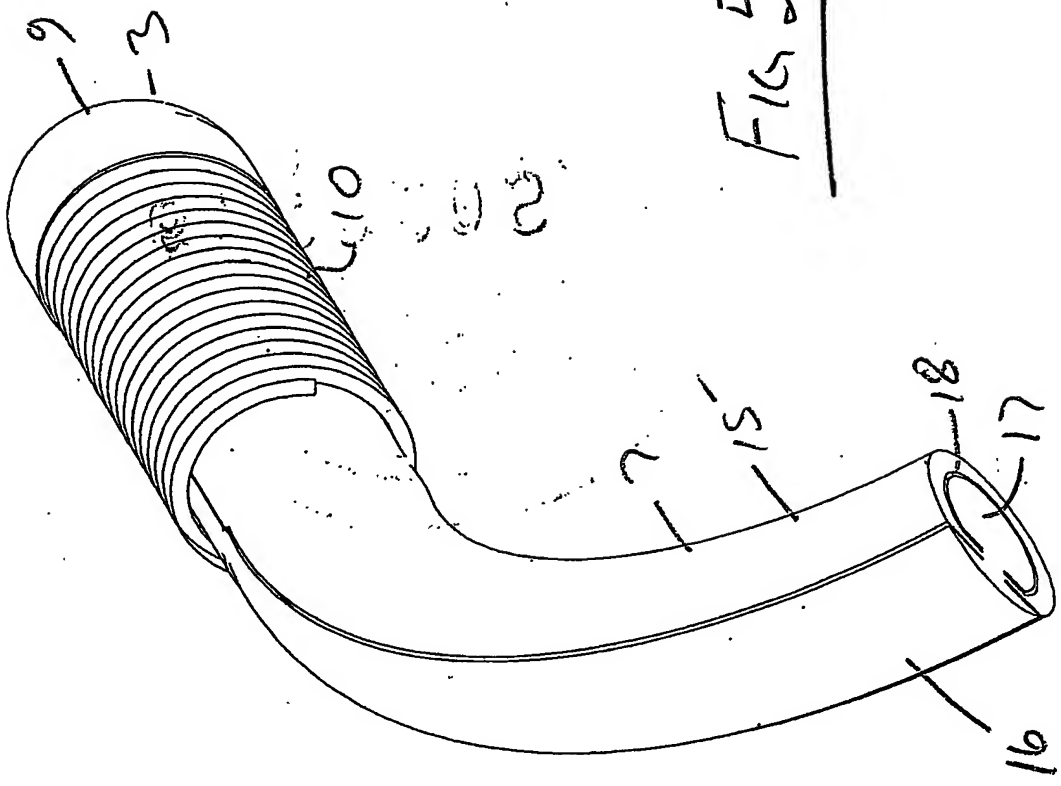

FIG 5